510（K）Summary of Safety and Effectiveness

This summary of 510k safety and effectiveness is being submitted in according with 21CFR part 807.92

1. Submitter: Edan Instruments, Inc
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AUG 3 0 2013

Prepare Date: Jun 13th, 2013

2. Proprietary Name: Vital Signs Monitor Models M3 and M3A

Classification Name: 21 CFR 870.1130 Noninvasive blood pressure measurement system
21 CFR 870.2700, Oximeter
21 CFR 880.2910 Clinical electronic thermometer

Product code: DQA, DXN, FLL

Classification: Class II

3. Predicate Devices:

- Edan Instruments Inc.: M3 and M3A Vital Signs Monitor K120144
- The Kendall Company: K003313

4. Device Description: The Vital Signs Monitor is a portable device intended for use by health care professionals. The monitor could provide the monitoring of physiological parameters such as the non-invasive blood pressure (NIBP), the oxygen saturation of the blood (SpO2) and Rectal/Oral/Auxiliary/Ear temperature measurement.

The following lists the detailed features of the subject device.

- LCD or LED display
- SpO2, Pulse Rate NIBP and TEMP measurement
- T2 or TH or F3000 module for Temp measurement
- Nellcor or EDAN SpO2 module
- Display numeric and waveform information simultaneously
- Nurse call feature

- Built-in Lithium-ion Battery
- Suitable for adult, pediatric and neonate patients
- Visual and audible alarm

5. Intended Use:

The Vital Signs Monitor models M3 and M3A (hereinafter called monitor) is intended to be used for non-invasive continuous monitoring of SpO2 (oxygen saturation of the blood), NIBP (non-invasive blood pressure) and TEMP (temperature).

The monitor is intended to be used only under regular supervision of clinical personnel. It is applicable to adult, pediatric, and neonatal usage in hospitals, hospital type facilities and intra-hospital moves.

The monitor is equipped with alarms that indicate system faults (such as loose or defective electrodes), physiologic parameters that have exceeded the limits set by the operator, or both

6. Effectiveness and Safety Considerations:

Clinical test: Clinical testing is not required.

Non-clinical test:

The following safety standards are conducted on the subject device based on the predicate version:
(1) IEC 60601-1 Electrical Safety
(2) IEC 60601-1-2 Electromagnetic Compatibility
(3) Clinical Electronic Thermometers testing for the newly added F3000 Temperature Module pursuant to the guidance "Guidance on the Content of Premarket Notification [510(K)] Submission for Clinical Electronic Thermometers" dated Mar. 1993.
(4) IEC 60601-2-49 Particular requirements for the safety of multifunction patient monitoring equipment

7. Comparison to predicate device

The M3 and M3A have the following similarities to devices which have previously received 510(k) concurrences:

- the same intended use
- use the similar operating principle
- use the same modules, including SpO2, NIBP and Quick TEMP (including infrared Ear TEMP)
- have the same or similar performance specifications

The differences between the subject devices and predicate devices do not affect the basic design principle, usage, effectiveness and safety of the subject devices. And no question is raised relating to

the safety and effectiveness. In summary, the M3 and M3A Vital Signs Monitor described in this submission is, in our opinion, substantially equivalent to the predicate devices.

8. Substantial Equivalent Conclusion:

Verification and validation testing were conducted on the Vital Signs Monitor Models M3 and M3A. This premarket notification submission demonstrates that Vital Signs Monitor Models M3 and M3A is substantially equivalent to the predicate device, and without any changes of the intended use compared to the predicate version.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 30, 2013

Edan Instruments, Inc.
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P.R. China

Re: K131818
Trade/Device Name: Vital signs monitor models M3 and M3A
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter, Blood-Pressure, Non-Nvasive
Regulatory Class: Class II
Product Code: DQA, DXN, FLL
Dated: July 26, 2013
Received: July 31, 2013

Dear Queena Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131818

Device Name: Vital Signs Monitor models M3 and M3A

The Vital Signs Monitor models M3 and M3A (hereinafter called monitor) is intended to be used for non-invasive continuous monitoring of SpO2 (oxygen saturation of the blood), NIBP (non-invasive blood pressure) and TEMP (temperature).

The monitor is intended to be used only under regular supervision of clinical personnel. It is applicable to adult, pediatric, and neonatal usage in hospitals, hospital type facilities and intra-hospital moves.

The monitor is equipped with alarms that indicate system faults (such as loose or defective electrodes), physiologic parameters that have exceeded the limits set by the operator, or both.

Prescription Use ___X___ AND/OR Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S
Date: 2013.08.30 15:02:56 -04'00'